

REMARKS

In response to the Final Office Action embodied in Paper No. 20071107, all the independent claims, 1, 29, and 36 have been amended to delete salts, esters and amides of choline magnesium trisalicylate to further emphasize the attributes of the base compound. Claims 1, 7, 29, 34-36, and 40 remain pending in the application. In light of these amendment and the lack of teaching in the prior art as to choline magnesium trisalicylate, reconsideration of the pending claims consistent with MPEP 2131.02.

Claims 1, 7, 29, 34-36, and 40 stand rejected under 35 U.S.C. §103(a) over Grilli et al. (WO 98/20864) in view of Bakhshi et al. (Journal of Neuro Oncology, 26, 133-9), and Myseros et al. (The rationale for glutamate antagonists in the treatment of traumatic brain injury, Ann NY Acad Sci, 1995, 765:262-271) and further in view of McGeer et al. (US 5,192,753).

Remarks Directed to Rejection of Claims 1, 7, 29, 34-36, and 40
Under 35 U.S.C. §103(a) over Grilli et al. in view of Bakhshi et al. and Myseros et al.
and further in view of McGeer et al. (US 5,192,753)

The articulation of the rejection is found in Paper No. 20071107, pages 4-8 and not reproduced herein for the sake of brevity, as well as the remarks made of record in the Amendment filed July 11, 2007.

The basis for the modification of the rejection articulated in Paper No. 20070416 to further include McGeer et al. is found in Paper No. 20071107, page 2, last full paragraph where it states: "The examiner respectfully notes that choline magnesium trisalicylate is considered a non-steroidal, anti-inflammatory salicylate drug (NSAID)." Applicant agrees that choline magnesium trisalicylate is within the genus of NSAIDs; however the requirements of MPEP 2131.02 are submitted to not preclude patentability of an undisclosed species when a genus is taught and the species is not "at once envisaged" from the genus as taught. Choline magnesium trisalicylate is respectfully submitted

to be a structure that is not within the genus teachings of Grilli et al. and as such, one of ordinary skill in the art would have to find a basis to equate choline magnesium trisalicylate with the NSAIDs found in Grilli et al. Choline magnesium trisalicylate is an NSAID, it has properties that render it suitable for the indication of neurotrauma (i.e. non-inhibition of platelets and protective effects of magnesium ions). The NSAIDs of Grilli et al. lack at least one of these properties and in fact are actually harmful in perpetuating the bleeding associated with neurotrauma.

While all NSAIDs have anti-inflammatory properties, all NSAIDs are not interchangeable. Specifically, the NSAIDs articulated in Grilli et al. (page 1, line 1- page 3, line 10) are largely inhibitory of platelet clotting thereby rendering them wholly unacceptable for the indications of the pending claims in which cerebral bleeding associated with neurotrauma. As such, Applicant respectfully requests that the claim language "non-inhibitory of platelets so as to reduce the inflammation associated with the neurotrauma" is entitled to patentable weight consideration in distinguishing the compounds articulated in Grilli et al. in the context of the pending method claims. Applicant wishes to reiterate that the pending claims are drawn to a method of treating specific indications and not to compounds per se.

Applicant's reference to MPEP 2131.02 is respectfully submitted to be relevant to understanding the teachings of Grilli et al. as to the compounds taught to be useful in treating inflammation associated with neurodegenerative disease. Applicant notes agreement with the Examiner that Grilli et al. in view of Bakhshi et al. and Myseros et al. "lack a teaching of choline magnesium trisalicylate" (paragraph two on page 7 of the Paper No. 20070416). As such, the structures of NSAIDs taught in these references are not those being claimed and further the indications taught in Grilli et al. in view of Bakhshi et al. and Myseros et al. and further in view of McGeer et al. are not concerned with bleeding associated with neurotrauma.

Perhaps the most striking basis for patentability relative to the teachings of the prior art reference combination is that administering a NSAID to a subject suffering neurotrauma without reference to the pending application teaching as to the requirement of non-inhibition of platelet clotting and the added protective effects of magnesium ions would invariably be lethal through continued bleeding within the brain.

The holding that McGeer et al. demonstrates an equivalence between choline magnesium trisalicylate and acetylsalicylic acid (aspirin) (Paper No. 20071107, page 7, last full paragraph) supports Applicant's position that the indications associated with neurotrauma recited in the pending method claims are entitled to patentable weight and are distinct from the pathology of neurodegenerative disease taught in the prior art combination. The administration to a subject suffering neurotrauma of aspirin would cause additional harm through perpetuating cerebral bleeding by platelet inhibition. (See instant specification page 9, lines 1-22). With respect to the pending claims there is no equivalency with aspirin and instead a contra-indication. As such, it is respectfully submitted that the teachings of the prior art references combination all teach the pathology of neurodegenerative disorder that lack the bleeding associated with neurotrauma per the pending claims. As the prior art lacks a teaching as to a NSAID treatment of neurotrauma, reconsideration of the pending claims is requested.

Bakhshi et al. in teaching the administration of CNS drugs via intrathecal catheter does not reach to the pending claims in terms of delivery of choline magnesium trisalicylate for the treatment of neurotrauma and instead discloses the application of the intrathecal catheter in the treatment of CNS tumors (Abstract) and with special emphasis on brain tumors. Treatment of a tumor lacks the immediacy of neurotrauma and indeed would be disfavored by one of skill in the

art as overly invasive when NSAIDs are tailored to promote oral and intravenous bioavailability across the blood-brain barrier.

Myseros et al. is submitted to lack a teaching relevant to the treatment of neurotrauma or neuronal injury and as such fails to bolster the limitations detailed in the other references of the prior art reference combination.

In view of the above remarks, reconsideration and the withdrawal of the rejection of claims 1, 7, 29, 34-36, and 40 under 35 U.S.C. §103(a) over Grilli et al. in view of Bakhshi et al. and Myseros et al. and further in view of McGeer et al. is solicited.

Summary

Claims 1, 7, 29, 34-36, and 40 are the claims pending in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested. Should the Examiner find to the contrary, he is respectfully requested to contact the undersigned attorney in charge of this application to resolve any remaining issues.

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Respectfully submitted,

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